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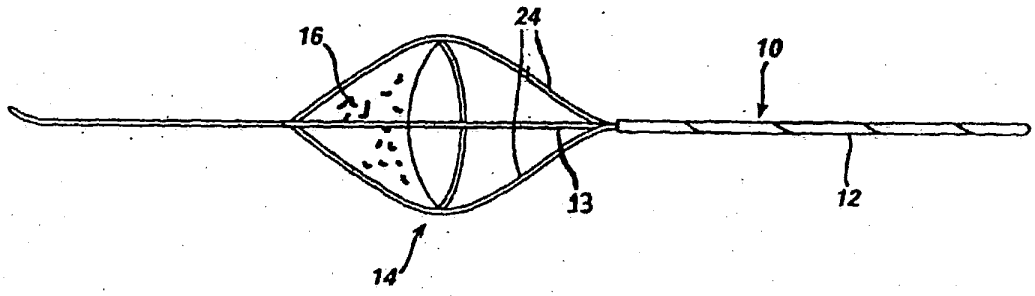
(54) Integral vascular filter system

(57) A integral vascular filter system comprising a multi-filament guidewire and an integral filter which may be used to capture embolic particulates during medical procedures, while allowing for continuous perfusion of blood. Filter activation is achieved via the use of a central core wire. The vascular filter system addresses the clinical problem of minimizing profile or diameter, so as to enable or facilitate the crossing of a lesion or obstruction in the vessel.

FIG. 1



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Description

[0001] The present invention relates to the treatment of vascular disease, and more particularly to an integral vascular filter system for use during medical procedures.

[0002] Percutaneous transluminal coronary angioplasty (PTCA), stenting and atherectomy are therapeutic medical procedures used to increase blood flow through the coronary arteries. These procedures may often be performed as alternatives to coronary bypass surgery. PTA (percutaneous transluminal angioplasty) and stenting may often be performed as alternatives to carotid endarterectomy, and femoral-popliteal bypass procedures. PTRA (percutaneous transluminal renal angioplasty) and stenting are procedures used to increase blood flow through the renal arteries, to address problems with renal function, and hypertension. In PTCA, PTA or PTRA procedures, the angioplasty balloon is inflated within the stenosed vessel, at the location of an occlusion, in order to shear and disrupt the wall components of the vessel to obtain an enlarged lumen. In stenting, an endoluminal prosthesis is implanted in the vessel to maintain patency following the procedure. In atherectomy, a rotating blade is used to shear plaque from the arterial wall.

[0003] One of the complications associated with all these techniques is the accidental dislodgment of plaque, thrombus or other embolic particulates generated during manipulation of the vessel, thereby causing occlusion of the narrower vessels downstream and ischemia or infarct of the organ which the vessel supplies. Such emboli may be extremely dangerous to the patient, and may result in myocardial infarction, stroke or limb ischemia. In 1995, Waksman et al. disclosed that distal embolization is common after directional atherectomy in coronary arteries and saphenous vein grafts. See Waksman et al., American Heart Journal 129(3): 430-5 (1995). This study found that distal embolization occurs in 28% (31 out of 111) of the patients undergoing atherectomy. In January 1999, Jordan, Jr. et al. disclosed that treatment of carotid stenosis using percutaneous angioplasty with stenting procedure is associated with more than eight times the rate of microemboli seen using carotid endarterectomy. See Jordan, Jr. et al. Cardiovascular Surgery 7(1): 33-8 (1999). Microemboli, as detected by transcranial Doppler monitoring in this study, have been shown to be a potential cause of stroke. The embolic materials include calcium, intimal debris, atheromatous plaque, and thrombi.

[0004] In order to initiate these procedures, one must first introduce a guidewire into the lumen of the vessel to serve as a conduit for other interventional devices, such as angioplasty balloons and stent delivery systems. This guidewire must be advanced into position past the location of the occlusion. Guidewires must be capable of traversing tortuous pathways within the body, consisting of bends, loops and branches. For this reason, guidewires need to be flexible, but they should also be sufficiently stiff to serve as a conduit for other devices. In addition, they must be "torqueable" to facilitate directional changes as they are guided into position. Guidewires are well known in the art, and are typically made of stainless steel, tantalum or other suitable materials, in a variety of different designs, for example, as disclosed in US-4545390, US-4619274, US-5095915 and US-6191365.

[0005] Vascular filters are also well known in the art, especially vena cava filters, as illustrated in US-4727873 and US-4688553. Vascular filters are often used during a postoperative period, when there is a perceived risk of a patient encountering pulmonary embolism resulting from clots generated peri-operatively. Pulmonary embolism is a serious and potentially fatal condition that occurs when these clots travel to the lungs. The filter is therefore typically placed in the vena cava to catch and trap clots before they can reach the lungs.

[0006] Many of the vascular filters in the prior art are intended to be permanently placed in the venous system of the patient, so that even after the need for the filter has passed, the filter remains in place for the life of the patient. US-3952747 discloses a stainless steel filtering device that is permanently implanted transvenously within the inferior vena cava. This device is intended to treat recurrent pulmonary embolism. Permanent implantation is often deemed medically undesirable, but it is done because filters are implanted in patients in response to potentially life-threatening situations.

[0007] To avoid permanent implantation, it is highly desirable to provide an apparatus and method for preventing embolization associated with angioplasty, stenting or other procedures. In particular, it is desirable to provide a device which may be temporarily placed within the vascular system to collect and retrieve plaque, thrombus and other embolic particulates which have been dislodged and/or developed as a result of angioplasty, stenting or other procedures. Such a device is removed at the end of the procedure. See, for example, US-5814064, US-5827324, US-5910154, US-6053932, US-6179861 and US-6001118.

[0008] One concern commonly encountered with all these devices is that the profile or outer diameter of the wire incorporating the filter tends to be substantially larger than the wire itself. In addition, many of the prior art devices require the use of a constraining sheath over the guidewire/filter assembly, which also increases the overall profile of the device. This larger profile may make it difficult to cross the lesion or obstruction in the vessel. If the guidewire with filter cannot cross the lesion or obstruction, the procedure must be done without a filter in place. This may lead to accidental dislodgment of plaque, thrombus or other embolic particulates generated during manipulation of the vessel, thereby causing occlusion of the narrower vessels downstream and ischemia or infarct of the organ which the vessel supplies. Such emboli may be extremely dangerous to the

patient, and may result in myocardial infarction, stroke or limb ischemia.

[0009] The prior art makes reference to the use of alloys such as Nitinol (Ni-Ti alloy), which have shape memory and/or superelastic characteristics, in medical devices that are designed to be inserted into a patient's body. The shape memory characteristics allow the devices to be deformed to facilitate their insertion into a body lumen or cavity, and then, when heated within the body, to return to their original shape. Superelastic characteristics, on the other hand, generally allow the metal to be deformed and restrained in the deformed condition to facilitate the insertion of the medical device containing the metal into a patient's body, with such deformation causing the phase transformation. Once within the body lumen, the restraint on the superelastic member may be removed, thereby reducing the stress therein so that the superelastic member may return to its original un-deformed shape by the transformation back to the original phase.

[0010] The prior art makes reference to the use of metal alloys having superelastic characteristics in medical devices which are intended to be inserted or otherwise used within a patient's body, for example as disclosed in US-4665905. Some guidewire designs have recommended the use of superelastic alloys, for example as disclosed in US-4925445 and US-4984581.

[0011] However, the prior art has yet to disclose any guidewires, made from Nitinol or other suitable materials, incorporating vascular filters, which may be used to address the clinical problem of minimizing profile or diameter, so as to facilitate the crossing of a lesion or obstruction in the vessel.

[0012] The present invention provides for an integral vascular filter system, which may be used to address the clinical problem of minimizing profile or diameter to enable or facilitate the crossing of a lesion or obstruction in the vessel, and which overcomes many of the deficiencies associated with the prior art devices, as briefly described above.

[0013] In accordance with one aspect, the present invention is directed to an integral vascular filter system comprising a multi-filament guidewire, a prescribed filter shape in the distal portion of the guidewire, and a porous covering attached to the prescribed filter shape in the distal portion of the guidewire. The prescribed filter shape may be formed from the multi-filaments of the distal portion of the guidewire. The distal portion of the guidewire has a smaller first diameter for insertion into a vessel, and a second larger diameter for expanding to substantially equal the diameter of the lumen of the vessel, and to be placed in generally sealing relationship with the lumen. The system further comprises an actuating core wire for causing the distal portion of the guidewire to move between the smaller first diameter, and the larger second diameter and prescribed filter shape.

[0014] In accordance with another aspect, the present invention is directed to an integral vascular filter system comprising a monofilament guidewire, a prescribed filter shape in the distal portion of the guidewire, and a porous covering attached to the prescribed filter shape in the distal portion of the guidewire. The prescribed filter shape may be formed from slots cut into the distal portion of the guidewire. The distal portion of the guidewire has a smaller first diameter for insertion into a vessel, and a second larger diameter for expanding to substantially equal the diameter of the lumen of the vessel, and to be placed in generally sealing relationship with the lumen. The system further comprises an actuating core wire for causing the distal portion of the guidewire to move between the smaller first diameter, and the larger second diameter and prescribed filter shape.

[0015] The integral vascular filter system enables or facilitates crossing lesions or obstructions in vessels by minimizing the profile or diameter of the overall system, due to the integral nature of the filter, and due to the elimination of the need for a constraining sheath over the guidewire / filter assembly. The filter is actuated through the use of a core wire, and is then used to capture embolic particulates released during a medical procedure. The filter is then collapsed, and the system is removed from the patient.

[0016] The advantage of the present invention is that the low profile or minimized diameter of the integral vascular filter system may enable or facilitate the crossing of lesions or obstructions in the vessel, which may not be crossable with other filter devices.

[0017] The integral vascular filter system of the present invention is designed to address the clinical problem of minimizing profile or diameter to enable or facilitate the crossing of a lesion or obstruction in the vessel. The device comprises a multi-filament guidewire having an outer diameter and an inner diameter, a distal end and a proximal end, a distal portion and a proximal portion, and a prescribed filter shape in the distal portion of the guidewire, the distal portion having a proximal end, a midpoint and a distal end, a smaller first diameter for insertion into the lumen of a vessel, and a larger second diameter for expanding to substantially equal the diameter of the lumen and to be placed in generally sealing relationship with the lumen; a porous covering having a distal end and a proximal end, with the distal end of the porous covering attached near the distal end of the prescribed filter shape, and the proximal end of the porous covering attached near the midpoint of the proximal filter shape; and an actuating core wire for causing the distal portion of the guidewire to move between the smaller first diameter and the larger second diameter and the prescribed filter shape. The integral vascular filter may be of sufficiently small profile or diameter to cross the lesion or occlusion, and may be placed distal to the occlusion to collect embolic particulates released during the procedure. Thereafter, the filter may be closed and removed from the patient, with the embolic particulates trapped within the filter.

[0018] Embodiments of the invention will now be described by way of example with reference to the accompanying drawings, in which:

Figure 1 is an simplified, cross-sectional view of an exemplary embodiment of the integral vascular filter system made from multi-filament wire, with the filter in the open position, in accordance with the present invention.

Figure 2 is an enlarged, partial cross-sectional view of an exemplary embodiment of the integral vascular filter system made from multi-filament wire, in accordance with the present invention.

[0019] Referring to the drawings, Figure 1 shows an integral vascular filter system 10 which comprises a guidewire 12, having a guidewire distal portion 14 with a prescribed filter shape. The guidewire distal portion 14 comprises a porous covering 16 attached to the guidewire distal portion 14. The guidewire is coaxially disposed around an actuating core wire 13. As illustrated in Figure 1, when the guidewire distal portion 14 achieves its larger second diameter and prescribed filter shape, the filter is in the open position. As illustrated in Figure 2, when the guidewire distal portion 14 achieves its smaller first diameter, the filter is in the closed position.

[0020] In accordance with an exemplary embodiment, as illustrated in Figures 1 and 2, the guidewire 12 may be a multi-filament wire. As illustrated in Figure 1, the guidewire distal portion 14 has a prescribed filter shape formed from the filaments 24 of the multi-filament wire. The guidewire distal portion 14 comprises a porous covering 16 attached to the guidewire distal portion 14. As illustrated in Figure 1, when the guidewire distal portion 14 achieves its larger second diameter and prescribed filter shape, the filter is in the open position.

[0021] As illustrated in Figures 1, and 2, the integral vascular filter system 10 may be used to cross lesions or obstructions in a vessel, and may then be used to collect and trap embolic particulates released during a medical procedure. The guidewire 12 is introduced into the lumen of the vessel, with the distal portion 14 in the closed position. The actuating core wire 13 may be used to prevent actuation of the filter by advancing it distally, while the integral vascular filter system 10 is being positioned in the vessel, with the guidewire distal portion 14 positioned past the lesion or occlusion. Other actuating means, such as guide catheters or other procedural devices may also be employed. Once the integral vascular filter system 10 is in position past the lesion or occlusion, the core wire 13 may be retracted to allow the guidewire distal portion 14 to achieve its larger second diameter and prescribed shape, with the porous covering 16 attached to the guidewire distal portion 14. At this point, other procedural devices, such as angioplasty balloons and stent delivery systems, may be introduced over the guidewire 12, to therapeutically treat the lesion or occlusion. Any embolic particulates released during the procedure may be captured in the porous covering 16 on the guidewire distal portion 14, while the pores in the porous covering allow distal perfusion of blood. When the therapeutic treatment of the lesion or occlusion is complete, the procedural devices may be withdrawn, and the core wire 13 may be advanced to return the guidewire distal portion 14 to its smaller first diameter. The guidewire 12 may then be removed from the lumen of the vessel.

[0022] The guidewire 12 may be made from any number of suitable materials, and is preferably made from stainless steel, or more preferably made from a shape memory alloy which exhibits superelastic properties, such as Nitinol. The guidewire 12 may be a multi-filament wire, and may comprise straight or, more preferably, twisted multi-filaments. The guidewire may alternatively be a monofilament guidewire, and the guidewire distal portion 14 may alternatively comprise any number or configuration of slots, and may preferably comprise longitudinal slots. The actuating core wire may be made from any number of suitable materials, and is preferably made from stainless steel or Nitinol. The Nitinol actuating core wire may further comprise a prescribed filter shape of its own formed by slots cut into the distal portion of the core wire. The porous covering 16 may be made from any number of suitable materials, and is preferably made from a flexible polymeric material with elastomeric properties chosen from a group consisting of polyurethane, polyethylene, silicone, nylon, polypropylene, PVC, or a co-polymer or mixture thereof. The porous covering 16 may also be made from a flexible metallic material, and is preferably made from a thin film Nickel Titanium material with superelastic and shape memory characteristics. The porous covering 16 may comprise any number and configuration of pores and may preferably comprises regularly-spacer laser-formed holes wherein the pore size is from about 20 to about 300 microns.

Claims

1. A vascular filter system for insertion into a lumen of a vessel, said vascular filter system comprising:

   a. a multi-filament guidewire having an outer diameter and an inner diameter, a distal end and a proximal end, a distal portion and a proximal portion;

   b. a prescribed filter shape in said distal portion of said guidewire, said prescribed filter shape comprising said multi-filaments of said distal portion of said guidewire; said prescribed filter shape having a proximal end, a midpoint and a distal end, a smaller first diameter for insertion into said lumen of said vessel, and a larger second diameter for expanding to substantially

equal the diameter of said lumen and to be placed in generally sealing relationship with said lumen;

c. a porous covering having a distal end and a proximal end, with said distal end of said porous covering attached near said distal end of said prescribed filter shape, and said proximal end of said porous covering attached near said midpoint of said prescribed filter shape; and

d. a generally solid actuating core wire for causing said prescribed filter shape to move between said smaller first diameter, and said larger second diameter, said core wire having a proximal end and a distal end, wherein said distal end of said prescribed filter shape is attached near said distal end of said core wire, and said guidewire is coaxially disposed around said core wire.

2. A vascular filter system for insertion into a lumen of a vessel, said vascular filter system comprising:

a. a guidewire having a distal end and a proximal end, a distal portion and a proximal portion, with said distal portion having a distal end, a midpoint and a proximal end;

b. a prescribed filter shape in said distal portion of said guidewire, said distal portion having a having a smaller first diameter for insertion into said lumen of said vessel, and a larger second diameter for expanding to substantially equal the diameter of said lumen and to be placed in generally sealing relationship with said lumen;

c. a porous covering having a distal end and a proximal end, with said distal end of said porous covering attached near said distal end of said distal portion of said guidewire, and said proximal end of said porous covering attached near said midpoint of said distal portion of said guidewire; and

d. actuating means for causing said distal portion of said guidewire to move between said smaller first diameter, and said larger second diameter and said prescribed filter shape.

3. The vascular filter system according to claim 1 or claim 2, wherein said guidewire is made from nickel-titanium based alloy.

4. The vascular filter system according to claim 1 or claim 2, wherein said guidewire is made from stainless steel alloy.

5. The vascular filter system according to claim 2, wherein said guidewire is made from polymeric material.

6. The vascular filter system according to claim 2, wherein said distal portion of said guidewire comprises a plurality of slots.

7. A vascular filter system for insertion into a lumen of a vessel, said vascular filter system comprising:

a. a multi-filament guidewire having an outer diameter and an inner diameter, a distal end and a proximal end;

b. a prescribed filter shape near said distal end of said guidewire, said prescribed filter shape comprising said multi-filaments of said guidewire; said prescribed filter shape having a proximal end, and a distal end, a smaller first diameter for insertion into said lumen of said vessel, and a larger second diameter for expanding to substantially equal the diameter of said lumen and to be placed in generally sealing relationship with said lumen;

c. a porous covering attached near said distal end of said prescribed filter shape; and

d. a generally solid actuating core wire for causing said prescribed filter shape to move between said smaller first diameter, and said larger second diameter, wherein said guidewire is coaxially disposed around said core wire.

8. The vascular filter system according to claim 15, wherein said guidewire is made from nickel-titanium alloy.

9. The vascular filter system according to claim 15, wherein said guidewire is made from stainless steel alloy.

10. The vascular filter system according to claim 15 wherein said prescribed filter shape achieves said smaller first diameter when said core wire is pushed distally to prevent said multi-filament wires from achieving said prescribed filter shape, and wherein said prescribed filter shape achieves said second larger diameter when said core wire is pulled proximally to allow said multi-filament wires to achieve said prescribed filter shape.

11. The vascular filter system according to claim 15, wherein said guidewire is a twisted multi-filament guidewire.

12. The vascular filter system according to claim 15, wherein a pore size of said porous covering is from about 20 to about 300 μm (microns).

13. A vascular filter comprising:

a. a guidewire having an outer diameter, a distal portion and a proximal portion, with said distal portion having a distal end, a midpoint and a

proximal end;

b. a filter placed in said distal portion of said guidewire, said filter distal portion having a shape with smaller first diameter for insertion into said lumen of said vessel, and a larger second diameter placed in generally sealing relationship with a body lumen;

c. a porous covering having a distal end and a proximal end, with said distal end of said porous covering attached near said distal end of said distal portion of said guidewire; and

d. actuating means for causing said distal portion of said guidewire to move between said smaller first diameter and said larger second diameter.

FIG. 1

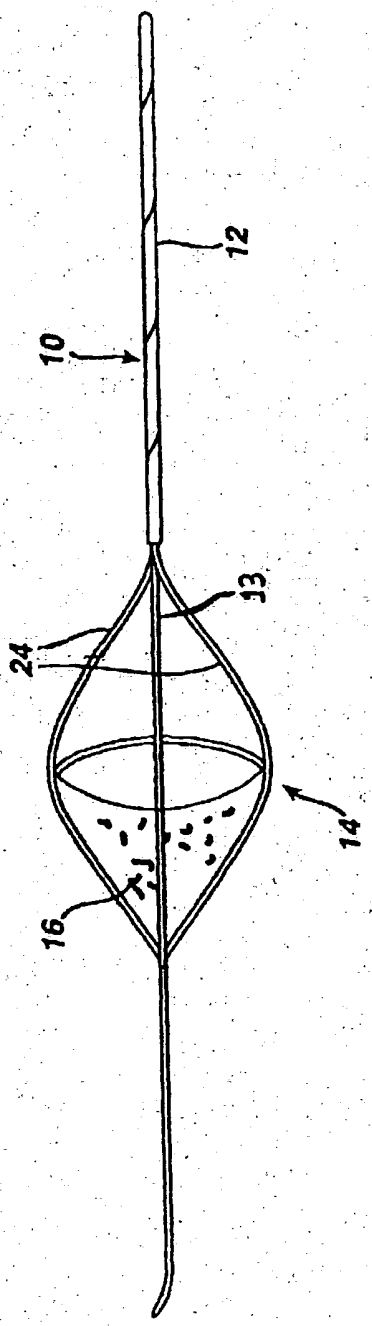

FIG. 2